REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested.

Claims 1, 6 and 17 have been amended, claims 2 and 21-54 have been canceled and new claims 55-72 have been added. Claims 37-54 have been canceled and new claims 55-72 have been added to more clearly and precisely claim the Applicants' invention as disclosed. Support for new claim 55 can be found in originally filed claim 6 and in paragraph 0012 of the specification as originally filed. Support for new claims 56-71 can be found in originally filed claims 37-54. Support for new claim 72 can be found in paragraph 0062 of the specification as originally filed. No new matter has been introduced as a result of the claim amendments.

Applicants reserve the right to pursue the subject matter of the canceled claims in one or more related applications.

35 U.S.C. §102 Rejections

Claims 1, 2, 5-9, 11-14, 16-18, 20-28, 30,32-34, 36, 37, 39-44, 46, 47, 49 and 53 stand rejected under 35 U.S.C. §102(e) as being anticipated by Rosenbluth. The Examiner predicates the rejection on the underlying assumption that the contents of Hubbell (US 5,410,016), have been incorporated by reference into the Rosenbluth specification. In support of this assertion the Examiner has drawn the Applicant's attention to paragraph [0065]. The Applicant respectfully disagrees for the following reasons.

In order for a reference to be incorporated by reference into a patent specification for all it discloses, or relevant portions thereof, 37 CFR §1.57(b) and MPEP §608.01(p)(I) require that "an incorporation by reference must be set forth in the specification and must: (1) Express a clear intent to incorporate by reference by using the root words "incorporate(s)" and "reference" (e.g., "incorporate by reference"); and (2) Clearly identify the referenced patent, application or publication."

In the present case, paragraph [0065] in Rosenbluth does not include clear language, as required by 37 CFR §1.57 and MPEP §608.01(p)(I), incorporating Hubbell into its specification and as such Hubbell, while descriptive of the prior art and academically interesting, is not *per se* incorporated by reference and does not make up part of the Rosenbluth specification. Thus, the contents of Hubbell are not available as prior art under section 102 of the Patent Act as the Examiner has presently chosen to assert them. That is, there is no "hybrid reference" that includes the contents of both Rosenbluth and Hubble in a single document as required by 35 U.S.C. §102(e). Had Rosenbluth desired to incorporate Hubbell into the specification he could have done so, but as evidenced by paragraph [065], Rosenbluth did not incorporate Hubbell's contents by referecne and the Patent Office is not free to do so *suis ponte.* Consequently, the Applicant respectfully asserts that the present rejection under 35 U.S.C. §102(e) does not meet the required legal standard and should be withdrawn. This rejection will not be addressed further. However, for the purposes of completeness, Applicants will address Rosenbluth alone for what Rosenbluth alone discloses.

Claims 37-54 have been canceled and re-presented as methods claims 56-72. Claim 56 is an independent claim corresponding to canceled claim 37. Claims 57-72 depend from claim 56. Applicants will address the pending rejections of claims 37-54 in light of the new claims.

Rosenbluth provides methods for treating or preventing endoleaks after an endovascular graft has been implanted. Rosenbluth discloses introducing expansile polymeric materials into the perigraft space such that the polymeric material expands *in situ* to substantially fill the perigraft space.

Applicant has amended independent claim 1. Claim 1 has been amended to claim, in part, "...at least one reservoir implanted adjacent to an aneurysmal site; at least one therapeutic agent within said reservoir; and at least one carrier provided within said reservoir, where the carrier delivers said therapeutic agent to said aneurysm site for the treatment of said aneurysmal tissue." New independent claim 56 claims "[a] method for the treating an aneurysm comprising: implanting a stent graft at an aneurysmal site; locating a reservoir remotely to said aneurysmal site; providing at least

one carrier having at least one therapeutic agent dispersed within said reservoir; and delivering said carrier and said therapeutic agent from said reservoir to said aneurysmal site for the treatment of said aneurysmal tissue.

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987)).

Rosenbluth does not disclose a reservoir. Furthermore, Rosenbluth does not disclose a reservoir comprising a carrier and a therapeutic agent. The expansile polymeric material disclosed in Rosenbluth is injected into the aneurysm sac between the other wall of a previously implanted stent graft and the inner wall of the vessel and allowed to fill the perigraft space. Rosenbluth does not disclose containing the polymeric material in a reservoir. Additionally, Rosenbluth does not disclose a method of treating an aneurysm in which the reservoir is located remotely to the aneurysm site.

Therefore, because each and every element as set forth in the instant claims, namely a device to treat an aneurysm comprising a reservoir having a carrier and a therapeutic agent provided within the reservoir, was not found, either expressly or inherently, in Rosenbluth et al., the pending claims are not anticipated under 35 USC §102(e). The Examiner is respectfully requested to withdraw the 35 USC §102(e) rejection of pending claims 1, 5-9, 11-14, 16-18 and 20 over Rosenbluth et al. in view of the amendments to independent claim 1, from which claims 5-9, 11-14, 16-18 and 20, depend, and Applicants' arguments *supra*.

Claims 1, 3, 4, 21 and 22 stand rejected under 35 U.S.C. §102(e) as being anticipated by Lax et al., US 2002/0065542. Claims 21 and 22 have been canceled as discussed *supra*.

Lax discloses an apparatus for treating an aneurysm in a vessel comprising an insertion member and a first electrode device coupled to the insertion member to apply electrical energy to an interior surface of the vessel to shrink the aneurysm. Lax

discloses treating leakages still occurring after treating the aneurysm with the disclosed device by back-filling the remaining void in the aneurysm with a biocompatible material.

Lax does not disclose a reservoir. Furthermore, Lax does not disclose a reservoir comprising a carrier and a therapeutic agent. The biocompatible material disclosed in Lax is injected into the aneurysm sac between the other wall of a previously implanted stent graft and the inner wall of the vessel and allowed to fill the aneurysm void. Lax does not disclose containing the biocompatible material in a reservoir. Additionally, Lax does not disclose a method of treating an aneurysm in which the reservoir is located remotely to the aneurysm site.

Therefore, because each and every element as set forth in the instant claims, namely a device to treat an aneurysm comprising a reservoir having a carrier and a therapeutic agent provided within the reservoir, was not found, either expressly or inherently, in Lax et al., the pending claims not anticipated under 35 USC §102(e). The Examiner is respectfully requested to withdraw the 35 USC §102(e) rejection of pending claims 1, 3 and 4 over Lax et al. in view of the amendments to independent claim 1, from which claims 3 and 4 depend, and Applicants' arguments *supra*.

Claims 1, 2, 3, 4, 6, 15, 19, 21, 22, 31, 37, 38, 48, 49, 53 and 54 stand rejected under 35 U.S.C. §102(e) as being anticipated by Bose et al. US 6,666,882. Claims 2, 21, 22, 31, 37, 38, 48, 49, 53 and 54 have been canceled as discussed *supra*.

Bose discloses devices for intra-cranial stenting for excluding aneurysms and treating atherosclerotic disease wherein the devices comprise an endoluminal sleeve. The endoluminal sleeve is located outside of the aneurysmal dilatations within the vessel and excludes the aneurysm from the circulation while reconstructing the lumen of the parent vessel. Bose also discloses that the endoluminal sleeve can be a thin film aneurysm occlusion device. Furthermore, the thin film aneurysm occlusion device can incorporate an intrinsic aneurysm volume-filling material or allow the introduction of extraneous aneurysm volume-filling materials, such as a shape memory material, to hold the aneurysm occlusion device in place.

Bose does not disclose a reservoir. Furthermore, Bose does not disclose a reservoir comprising a carrier and a therapeutic agent. The aneurysm volume-filling material disclosed in Bose is deployed into the aneurysm sac between the aneurysm occlusion device and the inner wall of the vessel and allowed to unravel to fill the aneurysm volume. Bose does not disclose containing the aneurysm volume-filling material in a reservoir. Additionally, Bose does not disclose a method of treating an aneurysm in which the reservoir is located remotely to the aneurysm site.

Therefore, because each and every element as set forth in the instant claims, namely a device to treat an aneurysm comprising a reservoir having a carrier and a therapeutic agent provided within the reservoir, was not found, either expressly or inherently, in Bose et al., the pending claims not anticipated under 35 USC §102(e). The Examiner is respectfully requested to withdraw the 35 USC §102(e) rejection of pending claims 1, 3, 4, 6, 15 and 19 over Bose et al. in view of the amendments to independent claim 1, from which claims 3, 4, 6, 15 and 19 depend, and Applicants' arguments *supra*.

Claims 37 and 50-52 stand rejected under 35 U.S.C. §102(b) as being anticipated by Alps et al. US 5,733,871.

Although claims 37 and 50-52 have been canceled, Applicants are addressing the rejection of these claims over Alps et al. in light of newly added claim 56-73.

Alps discloses methods for treating or preventing neuronal damage in the central nervous system comprising intravenously administering a pharmaceutical composition, specifically a neurotrophic factor, in a pharmaceutically acceptable carrier. In one example, the form of administration comprises an implantable polymer or membrane device in which the neurotrophic factor is encapsulated, or cells secreting the neurotrophic factor are encapsulated, and the implatable device is placed within the patient's brain or other appropriate locations in the body. Alps discloses that one medical condition for use of the method for preventing or treating neuronal damage is hemorrhage caused by rupture of aneurysms.

Alps does not disclose a device for treating an aneurysm. Alps only discloses treating or preventing neuronal damage resulting from hemorrhage due to aneurysm rupture. Furthermore, the reservoir disclosed by Alps does not delivery a therapeutic agent to an aneurysm site for the purpose of treating an aneurysm.

Therefore, because each and every element as set forth in the instant claims, namely a method of treating an aneurysm comprising implanting a stent graft, locating a reservoir remotely from the aneurysm site, providing a carrier and a therapeutic agent within the reservoir and delivering the carrier and the therapeutic agent to the aneurysm site, was not found, either expressly or inherently, in Alps et al., the pending claims are not anticipated under 35 USC §102(b).

Furthermore, Applicants believe that new claims 55-72 are also novel over the cited prior art as they incorporate the elements of originally filed claims 37-54 and have been amended consistent with the discussions *supra*.

35 U.S.C. §103 Rejections

Claims 10, 29 and 45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenbluth et al., US 2003/0014075. Claims 29 and 45 have been canceled.

To reject a claim under 35 USC §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. See *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1992). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. See *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed Cir. 1992). The Examiner must meet a three-part test to render a claimed invention *prima facie* obvious.

To begin with, the prior art references cited by the Examiner must provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the application." See *In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000). Where one reference is relied upon by the Examiner, there must be a suggestion or motivation to modify the teachings of that reference. *See id.* Where an obviousness determination relies on the combination of two or more references, there

must be some suggestion or motivation to combine the references. See *WMS Gaming Inc. v. International Game Technology*, 51 U.S.P.Q.2d 1386 (Fed. Cir. 1999). The suggestion may be found in implicit or explicit teachings within the references themselves, from the ordinary knowledge of one skilled in the art, or from the nature of the problems to be solved. *See id.*

Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. See *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The expectation of success, like the motivation to combine two prior art references, must come from the prior art, not the applicant's disclosure. *See id.*

Finally, the Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims, See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000).

If any one of these three factors is not met, the PTO has failed to establish a prima facie case of obviousness and the applicant is entitled to grant of a patent without making any affirmative showing of non-obviousness.

As discussed in detail *supra*, independent claim 1 is not anticipated under 35 U.S.C. §102(e) by Rosenbluth et al. Therefore claims dependent on claim 1 are not anticipated by Rosenbluth et al. Claim 10 is dependent on independent claim 1.

Rosenbluth does not teach or suggest all the elements of claim 10. Rosenbluth does not disclose a reservoir. Additionally, Rosenbluth does not disclose a reservoir comprising a carrier and a therapeutic agent. The expansile polymeric material disclosed in Rosenbluth is injected into the aneurysm sac between the other wall of a previously implanted stent graft and the inner wall of the vessel and allowed to fill the perigraft space. Rosenbluth does not disclose containing the polymeric material in a reservoir. Furthermore, Rosenbluth does not provide any suggestion or motivation to modify the disclosed expansile polymeric material to enclose the material in a reservoir.

Therefore the Examiner cannot establish *prima facie* obviousness of these claims. Accordingly, Applicants respectfully submit that claim 10 is not obvious under

35 USC §103(a) over Rosenbluth et al. and earnestly request the withdrawal of the outstanding rejection on this basis.

Conclusion

At the conclusion of the May 31, 2006 office action on pages 3 and 4, the Examiner states "[a]pplicant should note that not all possible claim rejections have been applied. For example, the lack of a rejection of a claim in view of prior art is not an indication that the claim is allowable over that prior art. In addition, applicant should note that numerous species have been presented and this application will likely be restricted at a future time period." Applicants respectfully request that the Examiner provide all rejections and restrictions to Applicants so as to conduct the prosecution of this application in an efficient manner for the benefit of both the Office and the Applicants.

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Respectfully submitted,

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